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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,904	09/18/2001	Jie Zhang	8747.82	8603

21999 7590 11/04/2003
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EXAMINER

GEORGE, KONATA M

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 11/04/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/954,904

Applicant(s)

ZHANG ET AL.

Examiner

Konata M. George

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on RCE filed on October 6, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17 and 19-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11-15 and 19-23 is/are rejected.
- 7) ☒ Claim(s) 7-10 and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15, 17 and 19-23 are pending in this application.

Request for Continued Examination (RCE)

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 6, 2003 has been entered.

Action Summary

2. The rejection of claims 1-6, 11-15 and 20-22 under 35 U.S.C. 102(b) over Argaud is being maintained for the reasons stated in the office action dated February 26, 2003.
3. The rejection of claims 1, 19 and 23 under 35 U.S.C. 103(a) over Argaud is being maintained for the reasons stated in the previous office action.

Response to Arguments

4. Applicant's arguments filed October 6, 2003 have been fully considered but they are not persuasive.

Applicants argue that the claimed invention includes a temperature modification apparatus designed to deliver a particular dose of drug at a pre-determined time at a

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pre-determined temperature range. It is argued that the prior art reference teaches an exothermic layer, which develops heat when exposed to air. It is the position of the examiner that the prior art does disclose those limitations. The prior art dosage of drug is amount of drug incorporated into the patch, the amount of heat and the amount of time the drug is release is dependent on the amount of time the air is in contact with the exothermic layer. Applicant has not shown in claim 1, how the temperature modification apparatus controls the amount of heat, drug and time of the drug delivery device.

Applicant argues that the prior art reference teaches uncontrolled exposure to oxygen whereas the claimed invention controls the amount of oxygen in the system. Claim 2 of the present invention teaches that there is a chamber that allows air to enter into the chamber, which is no different from the device of the prior art reference that also allows air into the device. There is no teaching in the claimed invention where the amount of air entering the device is controlled.

Conclusion

5. Claims 1-6, 11-15 and 19-23 stand rejected.
6. Claims 7-10 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (703) 308-4646. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Konata M. George

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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